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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/537,710

Applicant(s)

DAHLQVIST ET AL.

Examiner

Kathleen M. Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/21/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on October 1, 2003), Applicants filed a response and amendment received on April 5, 2004. Said amendment cancelled Claims 1-3, 5-23, 25, 28, 29, and 33-35 and amended Claims 30-32. Thus, Claims 30-32 are pending in the instant Office action and will be examined herein.

A supplemental response was filed on July 27, 2004 in response to the non-responsive action mailed April 5, 2004. Further amendments to Claim 30 were made.

Election

2. Applicant argues the restriction of record, made final in the previous Office action. Proper traversal of a restriction made final is in the form of a petition (see M.P.E.P. § 818.03(c)). Said restriction is considered proper for the reasons of record.

Applicant has cancelled all non-elected claims. Thus, Claims 30-32 are pending in the instant Office action and will be examined herein.

Priority

3. As previously noted, the instant application requests the benefit of priority for the foreign application 99106656.4 filed in Europe on April 1, 1999 in the declaration. A copy of this foreign document has been received, but it is not an official, ribboned copy. Without an official, ribboned copy, foreign priority cannot be granted.

Applicant commented in response that an initialed post card citing the receipt of the certified copy by the Office; however, no copy of a post card was received. Thus, foreign priority is not granted for the instant application.

As previously noted, the instant application is granted the benefit of priority for U.S. provisional applications 60/180,687 and 60/132,010 filed on February 7, 2000 and April 30, 1999, respectively. The instant application is also granted the benefit for U.S. non-provisional application 09/329,802 filed on June 10, 1999 as requested in the declaration.

Information Disclosure Statement

4. The information disclosure statement filed on June 21, 2004 fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Some references were not considered for the reasons described on the attached copy. All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto.

Declaration

5. In response to the previous holding that no post office addresses of inventors are listed on the filed declaration, Applicant filed a paper, in lieu of an application data sheet, listing said addresses.

Drawings

6. In response to the previous holding of informal drawings, Applicant filed formal drawings. Said drawings have been entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Compliance with the Sequence Rules

7. Previous request to comply with the sequence rules is maintained. Applicant filed a substitute sequence listing on April 5, 2004 containing 21 sequences; however, the specification describes, as amended to page 12 on April 5, 2004, 31 sequences (the Examiner notes below the typographical error listing two SEQ ID NO:29's). Thus, a new sequence listing is required that contains all 31 SEQ ID NOs.

Withdrawn - Objections to the Specification

8. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.

9. Previous objection to the amendment filed July 15, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment removing the new matter.

10. Previous objection to the specification for content placement is withdrawn by virtue of Applicant's amendment on July 27, 2004.

Maintained - Objections to the Specification

11. Previous objection to the specification for lacking complete continuity data in the first paragraph is maintained. Applicant argues that the amendment to the first paragraph corrects this error; this is not the case. The declaration requests priority not only to the cited provisional applications but also to U.S. non-Provisional Application No. 09/329,802, filed on June 10, 1999 and now abandoned. Thus, the first paragraph must also cite this priority request. Correction is required.

12. Previous objection to the Brief Description of the Drawings is maintained; Applicant presents no arguments. As previously noted, "the description of Figure 1 must be a description of Figures 1A and 1B. Similarly, of Figure 3 must be of Figures 3A, 3B, and 3C. Similarly, of Figure 4 must be of Figures 4A and 4B.

Also, the Tables previously filed with the drawings have not been filed with the set of formal drawings. Thus, the descriptions entered for Tab 1 and Tab 2 are wholly unclear in the absence of the table data. Correction and/or clarification is required.

13. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the Abstract is complete as written; the Examiner disagrees. As previously noted, "in many databases and in foreign countries, the Abstract is **crucial** in defining the disclosed subject matter, thus, its **completeness is essential**. The Examiner suggests the inclusion of the full name of the enzyme, phospholipid:diacylglycerol acyltransferase, and the source species, *S. cerevisiae*, *S. pombe*, *A. thaliana*, *N. crassa*, *Z. mays*,

and *L. esculentum*, for completeness” (emphasis added). The Examiner maintains that the Abstract is incomplete without description of the enzyme, by name, as well as description of the species taught in the specification. Correction is required.

14. Previous objection to the specification for being confusing in amendments is maintained. Applicant argues that the specification refers to amino acid sequences encoding SEQ ID NOs: 12 and 18; the Examiner disagrees that this clarifies the issues. The inconsistencies in the specification are summarized as follows:

- a) In an amendment filed on July 15, 2003 (Paper No. 26), the amendment to page 4 describes SEQ ID NO:18 (in its first occurrence) “Further, enzymes designated as PDAT comprising an **amino acid sequence** selected from the group consisting of sequences as set forth in SEQ ID No. 16, 17, and **18** are contemplated within the scope of the invention.” (emphasis added); however, SEQ ID NO:18 is a DNA sequence.
- b) In an amendment filed on July 15, 2003 (Paper No. 26), the amendment to page 21, 3rd line, notes a correlation “Further provisional and/or partial sequences are given as **SEQ ID NO. 16 through 19, respectively**” (emphasis added); however, the nature of this respective correlation is wholly unclear.
- c) In an amendment filed on July 15, 2003 (Paper No. 26), the amendment to page 21, last line, notes SEQ ID NO:12 is an amino acid, “Excluding this nucleotide would give **the amino acid sequence depicted in SEQ ID NO. 12**” (emphasis added); this is incorrect since SEQ ID NO:12 is an *L. esculentum*, DNA sequence.

Correction and/or clarification for each of these are required.

New Objections to the Specification

15. The specification is objected to for being confusing as two sequences are described by SEQ ID NO:29 in the amendment most recently filed. Clarification is required.

Withdrawn - Objections to the Claims

16. Previous objection to Claims 30-32 for containing non-elected subject matter is withdrawn by virtue of Applicant's amendment.
17. Previous objection to Claims 30-32 for depending from non-elected claims is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

18. Previous rejection of Claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "transgenic cell or organism" is withdrawn by virtue of Applicant's amendment to indicate both a transgenic cell or a transgenic organism.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

19. Previous rejection of Claims 31-32 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "using **the** nucleotide sequence of claim 7" (emphasis added) is withdrawn by virtue of Applicant's amendment clearly citing the scope of the nucleotide sequence intended.
20. Previous rejection of Claim 31 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "preferably, increased" is withdrawn by virtue of Applicant's amendment removing said phrase.

21. Previous rejection of Claim 32 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to recite method steps is withdrawn by virtue of Applicant's amendment to include particular method steps in the claim.

Maintained - Claim Rejections - 35 U.S.C. § 112

22. Previous rejection of Claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite is maintained. Applicants present no clear arguments as to why said phrases are clear.

To be specific, the amended Claim 30 has the following issues with respect to clarity:

- a) The phrase "contains a nucleotide sequence SEQ ID NO:1 from *S. cerevisiae*" (emphasis added) is unclear because the article "a" indicates more than one sequence (or any sequence) and SEQ ID NO:1 is a single sequence species.
- b) Equating "a nucleotide sequence" with "a DNA encoding" is confusing as it lacks parallel construction; both should recite nucleotide or both should recite DNA for clarity.
- c) The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See M.P.E.P. § 2173.05(d).
- d) The phrases following the "whereby" in the claim are wholly unclear. Are these meant to further limit the nucleotide sequence contained in the transgenic cell or organism? If so, the claim should read ---whereby said nucleotide sequence--- and "DNA" should be changed to ---nucleotide sequence---. Does the phrase beginning "in which" mean to define of function of the nucleotide sequence (or DNA)? Does the phrase beginning "said transgenic cells comprises" (which is improper English) mean to follow the previous "in which"? Moreover, it seems redundant. Thus, this entire section of the claim is wholly unclear.

Thus, Claim 30 must be written to clarify all of the above issues.

23. Previous rejection of Claims 31-32 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "uncommon" in its metes and bounds is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues: "Applicants believe "uncommon" fatty acids would be clear to one of ordinary skill in art. Applicants believe some latitude in claim language should be allowed by the examiner." This is not found persuasive because the claims must be clear as previously noted.

24. Previous rejection of Claims 30-32 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment to include only sequences with, at most, 95% identity to SEQ ID NO:2 overcomes the instant rejection; this is not the case, and the rejection is amended accordingly. It appears Applicant has employed, verbatim, the Examiner's suggestion. Unfortunately, the suggestion by the Examiner was to subject matter and not exact language (which would be indicated by quotes or dashes). Moreover, the omission of the inclusion of the functional PDAT language (suggested by the Examiner) necessitates the instant rejection. While the specification describes SEQ ID NO:1 and anything encoding SEQ ID NO:2, as well as related sequences encoding proteins having the same PDAT function, the specification does not describe related sequences, such as within the 95% identity, having different function. For these reasons, the rejection is herein maintained.

25. Previous rejection of Claims 30-32 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods of making triacylglycerol using a host organism transformed with a gene encoding PDAT from *S. cerevisiae* (SEQ ID NO:1), does not reasonably provide enablement for methods using any gene encoding any PDAT from any source absent any structural limitations is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the amendment to, at most, 95% identical to SEQ ID NO:1 obviates the instant rejection; the Examiner disagrees. As previously noted, "Having the instant disclosure in full view of the prior art, one of skill in the art would be unable to predict the structure of PDAT genes so as to be able to make them, even in the likeness of SEQ ID NO:1 (the *S. cerevisiae* sequence). Thus, the instant claims are not enabled to the full extent of their scope."

26. Previous rejection of Claims 31-32 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods to produce triacylglycerol, does not reasonably provide enablement for methods to produce triacylglycerol with uncommon fatty acids in organisms without the ability to natively produce triacylglycerol with uncommon fatty acids is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment to, at most, 95% identical to SEQ ID NO:1 obviates the instant rejection; the Examiner disagrees. As previously noted, "On page 1 of the specification, the invention as described as being able to produce uncommon fatty acids "in combination with a gene for the synthesis of an uncommon fatty acid"; the PDAT gene does not regulate this process. Thus, to effectively practice the claimed methods, one would be required to use organisms that naturally produce uncommon fatty acids or to use organisms also transformed with a gene for the synthesis of an uncommon fatty acid. The specification provides no guidance or working examples for producing uncommon fatty acids in the absence of uncommon fatty acid genes (either endogenous or exogenous). Thus, the instant claims are not enabled to the full extent of their scope."

27. Previous rejection of Claim 31 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods to produce triacylglycerol and other fatty acids, does not reasonably provide enablement for methods to produce host cells with *increased* overall oil content is maintained and altered to a full scope of enablement rejection by virtue of Applicant's amendment. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment to, at most, 95% identical to SEQ ID NO:1 obviates the instant rejection; the Examiner disagrees. As previously noted, "The instant specification describes methods that increase the fatty acid content of host cells wherein a PDAT gene is overexpressed (see page 19 and Table 2); the instant specification does not describe increasing the overall oil content of the host organism, which is a distinct method. As noted in WO96/38573 on page 1, "[c]urrently, there are no documented demonstrations of increased in oil content by transgenic means...[i]n contrast, increased in the proportions of some strategic fatty acids have been achieved by the introduction of various plant fatty acid biosynthesis and acyltransferase genes in oilseeds." The state of the art provides no examples to support the scope of the claimed invention." Thus, the claim is not enabled to any extent of its scope as amended to require increased oil content.

Withdrawn - Claim Rejections - 35 U.S.C. § 101

28. Previous rejection of Claims 30 and 32 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn by virtue of Applicant's amendment requiring transgenic organisms and/or transfection/transformation - all of which indicate the hand of man.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

29. Previous rejection of Claim 32 under 35 U.S.C. § 102(b) as being anticipated by Yu *et al.* as evidenced by Dahlqvist *et al.* is withdrawn by virtue of Applicant's amendment requiring transformation of the PDAT gene itself, which is not taught by Yu *et al.*

Maintained - Claim Rejections - 35 U.S.C. § 102

30. Previous rejection of Claim 30 under 35 U.S.C. § 102(b) as being anticipated by Yu *et al.* as evidenced by Dahlqvist *et al.* is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that Yu *et al.* teach a different enzyme; the Examiner does not disagree. However, the instant rejection is maintained because the claim reads on any transformed *S. cerevisiae*, not just *S. cerevisiae* transformed with SEQ ID NO:1 (note withdrawal of rejection of Claim 32 which clearly recites a transformation step). Moreover, the Dahlqvist *et al.* reference is used for evidence and need not pre-date Applicant's priority (see M.P.E.P. § 2131.01 and 2124).

Withdrawn - Claim Rejections - 35 U.S.C. § 103

31. Previous rejection of Claim 31 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Verhasselt *et al.* and Zou *et al.* is withdrawn by virtue of Applicant's amendment requiring increased oil content in the transformed cell. Such a limitation is not anticipated or rendered obvious by the prior art and is the subject of an enablement rejection above.

New - Claim Rejections - 35 U.S.C. § 103

32. Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Verhasselt *et al.* and Zou *et al.* considering the previously made rejection against Claim 31. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that Verhasselt *et al.* teach a sequence that is only 25% identical to an acyltransferase precursor in human. The Examiner fails to see the relevance. The sequence taught by Verhasselt *et al.* is SEQ ID NO:1. Verhasselt *et al.* assign a putative acyltransferase function, and Zou *et al.* obviate and motivate the methods using ORF N2042 as previously noted. Thus, the instant rejection is maintained.

Conclusion

33. Claims 30-32 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

April 1, 2005